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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,349	08/01/2003	Donald A. Sargent	ST8725US	3719
22203	7590	01/11/2005	EXAMINER	
KUSNER & JAFFE HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143			CHORBAJI, MONZER R	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,349	SARGENT ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 August 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/27/03, 8/24/04, 9/20/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This general action is in response to the application filing date received on 08/01/2003

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillebrenner et al (U.S.P.N. 5,534,221).

With respect to claims 1 and 7, the Hillebrenner reference discloses a container (44) for holding medical instruments to be sterilized in a device (42) such that the container includes a generally cup-shaped tray (64) that includes a bottom surface and a continuous sidewall. Further, the Hillebrenner reference teaches the following: a lid (62) that is attachable to the tray (figure, 4C, 64 and col.7, lines 32-37), valve means (86 and col.7, lines 11-16) with dual positions (valves are in opened position when the container 42 is placed within the cabinet 42 for a sterilization cycle and in closed position when container is removed from the cabinet 42 for storage) and a valve assembly associated with a passage into the cavity (figure 4C, unlabeled valve assembly that includes 108 and col.7, lines 54-56).

With respect to claims 2-5 and 8-11, the Hillebrenner reference discloses a container with two check valves (80 and 82) that inherently includes resilient flexible element. The container of the Hillebrenner reference includes a tray having a closed valve when not in the

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sterilization device (col.7, lines 14-17) such that the device must inherently includes an external actuator element for moving the valves on the container from a closed position to an open position when the container is placed in the device for sterilization to occur. The Hillebrenner reference discloses two passages into the container with associated valve assemblies (figure 4C, 104 and 108).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al (U.S.P.N. 5,534,221).

The teachings of the Hillebrenner reference have previously been set forth with respect to claims 1-5 and 7-11. However, with respect to claim 6, the Hillebrenner reference discloses a container (44) with two valve elements (80 and 82) that are independently movable between an open position (container 44 is placed in device 42) and a closed position (container is used to store the sterilized medical instrument) such that, for example, closing the valve assembly (unlabeled structure leading to line 110 in figure 4C) would close opening (108) in tray (64). Modifying the number of valves associated with the container is a matter of routine experimentation. For example, increasing the number of valves would enable one skilled in the art to sterilize more instruments per batch.

7. Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al (U.S.P.N. 5,534,221) in view of Siegel et al (U.S.P.N. 5,217,698).

With respect to claim 12, the Hillebrenner reference discloses a container for holding medical instruments to be sterilized such that the container includes a valve (86 and col.7, lines 11-16) with dual positions (valves are in opened position when the container 42 is placed within the cabinet 42 (for example, a deactivation chamber) for a sterilization cycle and in closed position when container is removed from the cabinet 42 for storage). The container of the Hillebrenner reference includes a valve in closed

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position when not in the sterilization device (col.7, lines 14-17) such that the device must inherently include an actuator element for moving the valve on the container from a closed position to an open position when the container is placed in the device for sterilization to occur. However; the Hillebrenner reference fails to disclose a circulation system. The Siegel reference, which is in the art of sterilizing medical instruments, teaches the use of a circulation system (col.5, lines 62-68 and col.6, lines 1-26). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of the Hillebrenner reference to include a circulation system as taught by the Siegel reference in order to insure that all the internal surfaces of the device after a sterilization cycle are disinfected (col.6, lines 27-37).

With respect to claims 13 and 19-20, the Siegel reference discloses inlet and outlet ports (114 and 52) on both the cassette and the chamber when the cassette is disposed into the chamber (col.8, lines 8-9). Further, the Siegel reference discloses a closed loop liquid sterilant circulation system (col.6, lines 27-40).

The features of claims 14-16 have previously been addressed above with respect to claims 2-5 and 8-11.

With respect to claims 17-18, the Hillebrenner reference discloses a chamber (42) into which the container (44) is placed for connection (50 and 48) to inlet and outlet ports. When the container is placed in the chamber, both ports on the container are moved to an open position for sterilization to occur through a corresponding inlet and outlet ports in wall of the chamber. Having a movable or flexible inlet and outlet ports in the wall of the chamber is a matter of routine experimentation in order to insure proper

connection between the sterilant source and the container even though if the container was not placed in the exact position within the chamber.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Langford reference (U.S.P.N. 5,906,802) discloses valves on a container with open and closed position.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.
10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AU 1744
01/05/2005

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